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| 10/670,871 | 09/25/2003 | Lid B. Wong | BIO1819P0051US | 5787 | | |
| 32116 75 | 32116 7590 01/27/2005 | | | EXAMINER | | |
| • | LIPS, KATZ, CLARK | GEISEL, | GEISEL, KARA E | | | |
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| | | | | DATE MAILED: 01/27/2005 | | |

Please find below and/or attached an Office communication concerning this application or proceeding.

| J.S. Patent and T PTOL-326 (R | | ction Summary | | Part of Paper No./I | Mail Date 0105 | | |
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| 2) Notice 3) Information Paper | ce of References Cited (PTO-892) ce of Draftsperson's Patent Drawing Review (PTO-948) mation Disclosure Statement(s) (PTO-1449 or PTO/SB/08) er No(s)/Mail Date | | Interview Summary Paper No(s)/Mail Da Notice of Informal P Other: | ate | O-152) | | |
| a) | Acknowledgment is made of a claim for foreign All b) Some * c) None of: 1. Certified copies of the priority document 2. Certified copies of the priority document 3. Copies of the certified copies of the priority document application from the International Bureausee the attached detailed Office action for a list | ts have been to ts have been to rity document u (PCT Rule | received. received in Applicati s have been receive 17.2(a)). | on No ed in this Nationa | l Stage | | |
| Priority u | under 35 U.S.C. § 119 | | | | | | |
| 9)□ 10)⊠ | The specification is objected to by the Examine The drawing(s) filed on 12 November 2004 is/a Applicant may not request that any objection to the Replacement drawing sheet(s) including the correct The oath or declaration is objected to by the Example 1. | are: a) acc drawing(s) be tion is required | held in abeyance. See if the drawing(s) is obj | e 37 CFR 1.85(a). jected to. See 37 C | FR 1.121(d). | | |
| 5)□ 6)⊠ | Claim(s) is/are allowed. Claim(s) <u>1-23</u> is/are rejected. Claim(s) is/are objected to. | | | | | | |
| - | Claim(s) <u>1-25</u> is/are pending in the application 4a) Of the above claim(s) <u>24 and 25</u> is/are with | | onsideration | | | | |
| Disposit | ion of Claims | | | | | | |
| -, | closed in accordance with the practice under E | | | | | | |
| 2a)□ 3)□ | his action is FINAL . 2b) This action is non-final. Ince this application is in condition for allowance except for formal matters, prosecution as to the merits is | | | | | | |
| 1)⊠ 2a)⊠ | Responsive to communication(s) filed on <u>12 N</u> This action is FINAL . 2b) This | | | | | | |
| Status | | | | | | | |
| THE - Exte after - If the - If NC - Failu | ORTENED STATUTORY PERIOD FOR REPLY MAILING DATE OF THIS COMMUNICATION. Insions of time may be available under the provisions of 37 CFR 1.15 SIX (6) MONTHS from the mailing date of this communication. It is period for reply specified above is less than thirty (30) days, a reply period for reply is specified above, the maximum statutory period were to reply within the set or extended period for reply will, by statute reply received by the Office later than three months after the mailing ed patent term adjustment. See 37 CFR 1.704(b). | 36(a). In no event, y within the statutor will apply and will e e, cause the applica | however, may a reply be time y minimum of thirty (30) days xpire SIX (6) MONTHS from tion to become ABANDONE | nely filed s will be considered time the mailing date of this of D (35 U.S.C. § 133). | | | |
| Period fo | or Reply | | | | | | |
| | The MAILING DATE of this communication app | Kara E Geiso | | orrespond no a | ddross | | |
| Office Action Summary | | Examiner | | Art Unit | | | |
| | | 10/670,871 | | WONG ET AL. | | | |
| | | Applicati n | INO. | Applicant(s) | | | |

DETAILED ACTION

Claim Objections

Claim 14 is objected to because of the following informalities: minor typographical error.

In regards to claim 14, line 20, "focal sport" should be corrected to --focal spot--. Appropriate correction is required.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless -

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claim 23 is rejected under 35 U.S.C. 102(b) as being anticipated by Zarling et al. (USPN 5,736,410), previously cited.

In regards to claim 23, Zarling discloses a method for identifying a pharmaceutically active compound (column 7, lines 26-38 and column 11, lines 14-28) comprising interacting a compound with a specimen (column 10, lines 37-54) containing at least three chemicals of interest (column 35, lines 41-53), and simultaneously detecting the activities of the at least three chemicals from optical signals simultaneously emitted from a single focal spot (fig. 6, 115 and column 36, lines 1-8) on the specimen (columns 35-36, lines 41-67 and 1-19 respectively).

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject

Art Unit: 2877

matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 1-2, 4-5, 15-16, and 18-20 are rejected under 35 U.S.C. 103(a) as being unpatentable over Zarling et al. (USPN 5,736,410) in view of Oshida et al. (US Pub 2002/0140933), both previously cited.

In regards to claims 1 and 15, Zarling discloses an apparatus and method for screening a compound (fig. 6) by monitoring the interactions of the compound with a specimen having fluorophore loaded target cells (column 35, lines 41-53), comprising an optical illumination unit comprising one or more LED light sources (85a-c and column 32, lines 51-54), each of which generates a particular wavelength of light that is couples to each fluorophore (column 35, lines 49-53) wherein light from the light sources is directed to illuminate the specimen (sample), a fluorescence separation unit (120a-c) coupled to receive emitted light simultaneously from each fluorophore at a single focal spot (115 and column 36, lines 1-8) on the specimen and separate at least three emitted wavelengths of light from the emitted light (column 36, lines 5-15), and a fluorescence detection unit (125a-c) coupled to the fluorescence separation unit to measure the at least three wavelengths of emitted light. It is not disclosed that the fluorescence detection unit counts photons emitted by the three wavelengths of light.

Oshida discloses a similar apparatus (fig. 1) for screening a compound by monitoring the interactions of the compound with a specimen having fluorophore loaded target cells (page 1, \P 2). Oshida teaches to use photon counting when weak fluorescence is detected in order to get a measurement

Art Unit: 2877

of the fluorescence (page 1, ¶ 10). Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to have Zarling's fluorescence detection unit count photons emitted by the three wavelengths of light in order to get a measurement of fluorescence at the three wavelengths, even if the fluorescence is weak.

In regards to claims 2 and 16, the combined apparatus further includes a light-processing unit coupled to the light sources, the light processing unit altering the qualities of the light beam from the light sources (Zarling column 30, lines 50-63).

In regards to claim 4, the fluorescence separation unit further comprises at least three band limited interference filters (Zarling fig. 30 D12 and column 39, lines 35-49).

In regards to claim 5, the apparatus further comprises at least three photodetectors coupled to receive the at least three wavelengths of emitted light (Zarling fig. 6, 125a-c).

In regards to claim 18, Zarling discloses focusing light from the light source onto the specimen (Zarling column 36, lines 1-8).

In regards to claim 19, Zarling discloses filtering the first, second, and third wavelengths of light (fig. 6, 120a-c).

In regards to claim 20, the combined apparatus would generate a count of photons from the first, second, and third wavelengths of lights (Oshida page 1, ¶ 10).

Claims 1-23 are rejected under 35 U.S.C. 103(a) as being obvious over Mao et al. (US Pub 2003/0228566), previously cited.

The applied reference has a common inventor with the instant application. Based upon the earlier effective U.S. filing date of the reference, it constitutes prior art only under 35 U.S.C. 102(e). This rejection under 35 U.S.C. 103(a) might be overcome by: (1) a showing under 37 CFR 1.132 that any invention disclosed but not claimed in the reference was derived from the inventor of this application and is thus not an invention "by another"; (2) a showing of a date of invention for the claimed subject matter

Art Unit: 2877

of the application which corresponds to subject matter disclosed but not claimed in the reference, prior to the effective U.S. filing date of the reference under 37 CFR 1.131; or (3) an oath or declaration under 37 CFR 1.130 stating that the application and reference are currently owned by the same party and that the inventor named in the application is the prior inventor under 35 U.S.C. 104, together with a terminal disclaimer in accordance with 37 CFR 1.321(c). For applications filed on or after November 29, 1999, this rejection might also be overcome by showing that the subject matter of the reference and the claimed invention were, at the time the invention was made, owned by the same person or subject to an obligation of assignment to the same person. See MPEP § 706.02(l)(1) and § 706.02(l)(2).

In regards to claims 1 and 15, Mao discloses an apparatus and method for screening a compound (fig. 2) by monitoring the interactions of the compound with a specimen having fluorophore loaded target cells (page 2, ¶ 22), comprising an optical illumination unit comprising one or more light sources (fig. 2, 102, 108), each of which generates a particular wavelength of light that is coupled to each fluorophore (page 3, ¶ 27) wherein light from the at least two light sources is directed to illuminate the specimen (fig. 2, 114), a fluorescence separation unit (fig. 2, 118) coupled to receive emitted light simultaneously from each fluorophore at a single focal spot (fig. 1, 116 and page 3, ¶ 30) from the specimen and separate at least three emitted wavelengths of light from the emitted light (page 3, ¶ 27), and a fluorescence detection unit (fig. 2, 128) coupled to the fluorescence separation unit to count photons emitted by the at least three wavelengths of emitted light (page 3, ¶ 27). It is not disclosed that the light sources are one or more LED light sources. It would have been obvious to one having ordinary skill in the art at the time the invention was made to replace the Xenon lamp and Argon laser with LED light sources since replacing the lamp and laser with LED light sources would be more cost effective, and furthermore, the examiner takes Official Notice of the equivalence of LED light sources and Xenon lamps and Argon lasers for their use as a light source for exciting a fluorophore, and the selection of any of these known equivalents to excite a fluorophore would be within the level of ordinary skill in the art (see prior art below).

Art Unit: 2877

In regards to claim 2, the optical illumination unit further comprises a light-processing unit coupled to the light sources, the light processing unit altering the qualities of a light beam from the light sources (page 3, ¶ 29).

In regards to claim 3, the apparatus further comprises at least two dichroic mirrors coupled to the optical illumination unit (fig. 2, 210, 214).

In regards to claim 4, the fluorescence separation unit further comprises at least three bandlimited interference filters (fig. 2, 234, 250, 256).

In regards to claim 5, the apparatus further comprises at least three photodetectors coupled to receive the at least three wavelengths of emitted light (fig. 2, 260, 264, 268).

In regards to claim 6, Mao discloses an apparatus for screening a compound (fig. 2) by monitoring the interactions of the compound with a specimen having fluorophore-loaded target cells (page 2, ¶ 22), comprising an optical illumination unit comprising one or more light sources (fig. 2, 104, 108), each of which generates a particular wavelength of light that is coupled to each fluorophore (page 3, ¶ 27), a plurality of filters coupled to the optical illumination unit to coaxially illuminate the specimen (fig. 2, 210, 214), a fluorescence separation unit comprising at least two filters (fig. 2, 224, 240) to direct and separate at least three emitted wavelengths of light from the light simultaneously emitted from the fluorophore at a single focal spot on the specimen (fig. 1, 116 and page 3, ¶ 30), and a fluorescence detection unit comprising at least three detectors (fig. 2, 260, 264, 268), each of the detectors comprising a photo-detector. It is not disclosed that the light sources are one or more LED light sources. It would have been obvious to one having ordinary skill in the art at the time the invention was made to replace the Xenon lamp and Argon laser with LED light sources since replacing the lamp and laser with LED light sources would be more cost effective, and furthermore, the examiner takes Official Notice of the equivalence of LED light sources and Xenon lamps and Argon lasers for their use as a light source for

Art Unit: 2877

exciting a fluorophore, and the selection of any of these known equivalents to excite a fluorophore would be within the level of ordinary skill in the art (see prior art below).

In regards to claim 7, the apparatus further comprises a light-processing unit coupled to a light source for altering the qualities of a light beam from the light source (page 3, ¶ 29).

In regards to claim 8, the apparatus further comprises an inverted microscope coupled to receive light emitted from the specimen (fig. 2).

In regards to claim 9, the apparatus further comprises a computer coupled to the fluorescence detection unit (fig. 2, 136).

In regards to claim 10, Mao discloses an apparatus for screening a compound (fig. 2) by monitoring its interactions with a specimen having fluorophore-loaded target cells (page 2, ¶ 22), comprising at least one light source (fig. 2, 104) that generates light of a particular wavelength that is coupled to a particular fluorophore (page 3, ¶ 27), a first dichroic mirror coupled to receive light from the light source and to deflect light from the light source to the specimen (fig. 2, 114) and pass wavelengths of light simultaneously emitted from the fluorophores at a single focal spot on the specimen (fig. 2, 220 and fig. 1, 116 and page 3, ¶ 30), a second dichroic mirror that deflects a first wavelength of light from the wavelengths of light simultaneously emitted from fluorophores at a single focal spot on the specimen (fig. 2, 224), a third dichroic mirror that deflects a second wavelength of light from the wavelengths of light simultaneously emitted from fluorophores at a single focal spot on the specimen and passes a third wavelength of light from the specimen (fig. 2, 240), at least three band-limited interference filters (fig. 2, 234, 250, 256), and at least three photodetectors coupled to receive outputs associated with the first, second, and third wavelengths of light (fig. 2, 260, 264, 268). It is not disclosed that the light sources are one or more LED light sources. It would have been obvious to one having ordinary skill in the art at the time the invention was made to replace the Xenon lamp and Argon laser with LED light sources since replacing the lamp and laser with LED light sources would be more cost effective, and furthermore, the

Art Unit: 2877

examiner takes Official Notice of the equivalence of LED light sources and Xenon lamps and Argon lasers for their use as a light source for exciting a fluorophore, and the selection of any of these known equivalents to excite a fluorophore would be within the level of ordinary skill in the art (see prior art below).

In regards to claim 11, the apparatus further comprises a light-processing unit (page 3, \P 29).

In regards to claim 12, the apparatus further comprises an inverted microscope coupled to receive light emitted from the specimen (fig. 2).

In regards to claim 13, the apparatus further comprises a computer coupled to receive outputs of the at least three photodetectors (fig. 2, 136).

In regards to claims 14 and 22, Mao discloses an apparatus and method for screening a compound (fig. 2) by monitoring its interactions with a specimen having fluorophore-loaded target cells (page 2, ¶ 22) to develop a profile of target cells in a specimen, comprising at least one light source which generates a particular wavelength of light (fig. 2, 104, 108), a first dichroic mirror coupled to receive light from the light source (fig. 2, 210), a second dichroic mirror (fig. 2, 224) that deflects a first wavelength of light from the wavelengths of light simultaneously emitted from fluorophores at a single focal spot on the specimen (fig. 1, 116 and page 3, ¶ 30), a third dichroic mirror that deflects a second wavelength of light from the light emitted form the specimen and passes a third wavelength of light from wavelengths of lights simultaneously emitted from the fluorophore at a single focal spot on the specimen (fig. 2, 240), at least three band-limited interference filters (fig. 2, 234, 250, 256), at least three photodetectors coupled to receive outputs associated with the first, second, and third wavelengths of light (fig. 2, 260, 264, 268) and a computer coupled to receive outputs of the three photodetectors (fig. 2, 136). It is not disclosed that the light sources are one or more LED light sources. It would have been obvious to one having ordinary skill in the art at the time the invention was made to replace the Xenon lamp and Argon laser with LED light sources since replacing the lamp and laser with LED light sources would be more cost effective, and

furthermore, the examiner takes Official Notice of the equivalence of LED light sources and Xenon lamps and Argon lasers for their use as a light source for exciting a fluorophore, and the selection of any of these known equivalents to excite a fluorophore would be within the level of ordinary skill in the art (see prior art below).

In regards to claim 16, the method further comprises a step of filtering light from the light source (fig. 2, 202).

In regards to claim 17, the method further comprises a step of expanding light from the light source (fig. 5, 506).

In regards to claim 18, the method further comprises a step of focusing light from the light source on the specimen (fig. 5, 512).

In regards to claim 19, the method further comprises a step of filtering the first, second and third wavelengths of light (fig. 5, 522).

In regards to claim 20, the method further comprises a step of generating a count of photons from the first, second, and third wavelengths of light (fig. 5, 528).

In regards to claim 21, the method further comprises a step of generating a response profile of the target cells (fig. 5, 530).

In regards to claim 23, Mao discloses a method for identifying a pharmaceutically active compound (page 1, \P 2) comprising interacting a compound with a specimen containing at least three chemicals of interest (page 2, \P 22), and simultaneously detecting the activities of the at least three chemicals from optical signals simultaneously emitted from a single focal spot on the specimen (fig. 3 and fig. 1, 116 and page 3, \P 30).

Additional Prior Art

Art Unit: 2877

The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. The prior art of record is Fernandez (USPN 6,485,981), Tokuda (US Pub 2003/0155528), Lawrence et al. (US Pub 2003/0224526), McNeil, III et al. (US Pub 2004/0098202).

Fernandez teaches using either LED light sources or argon lasers to excite a fluorophore.

Tokuda teaches replacing a xenon lamp with LED light sources to increase the stability of an excitation light source.

Lawrence teaches using either LED light sources or argon lasers to excite a fluorophore.

McNeil teaches using either LED light sources or argon lasers to excite a fluorophore.

Response to Arguments

Applicant's arguments with respect to claims 1-23 have been considered but are moot in view of the new ground(s) of rejection.

Conclusion

Several facts have been relied upon from the personal knowledge of the examiner about which the examiner took Official Notice in this Office Action. Applicant must seasonably challenge well known statements and statements based on personal knowledge when they are made by the Board of Patent Appeals and Interferences. In re Selmi, 156 F.2d 96, 70 USPQ 197 (CCPA 1946); In re Fischer, 125 F.2d 725, 52 USPQ 473 (CCPA 1942). See also In re Boon, 439 F.2d 724, 169 USPQ 231 (CCPA 1971) (a challenge to the taking of judicial notice must contain adequate information or argument to create on its face a reasonable doubt regarding the circumstances justifying the judicial notice). If applicant does not seasonably traverse the well-known statement during examination, then the object of the well-known statement is taken to be admitted prior art. In re Chevenard, 139 F.2d 71, 60 USPQ 239 (CCPA 1943). A seasonable challenge constitutes a demand for evidence made as soon as practicable during prosecution. Thus, applicant is charged with rebutting the well-known statement in the <u>next reply</u> after the Office action in which the well-known statement was made.

Art Unit: 2877

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, THIS ACTION IS MADE FINAL. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Kara E Geisel whose telephone number is 571 272 2416. The examiner can normally be reached on Monday through Friday, 8am to 4pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gregory J. Toatley, Jr. can be reached on **571 272 2800 ext. 77**. The fax phone numbers for the organization where this application or proceeding is assigned are 703 872 9306 for regular communications and 703 872 9306 for After Final communications.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Primary Examiner
Art Unit 2877

Page 12

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January 20, 2005